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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO.   |
|---|-------------|----------------------|-------------------------------|--------------------|
| 09/497,422  | 02/03/2000  | Stephen A. Berry     | ARC2914 US R1<br>(3139-6169U) | 7482               |
| 7590  | 05/01/2006  |                      |                               | EXAMINER           |
| Edgar R. Cataxinos<br>TraskBritt, PC<br>PO Box 2550<br>Salt Lake City, UT 84110 |             |                      |                               | FUBARA, BLESSING M |
|   |             |                      | ART UNIT                      | PAPER NUMBER       |
|   |             |                      |                               | 1618               |

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| <b>Office Action Summary</b> | <b>Application No.</b>         | <b>Applicant(s)</b> |
|------------------------------|--------------------------------|---------------------|
|                              | 09/497,422                     | BERRY ET AL.        |
|                              | Examiner<br>Blessing M. Fubara | Art Unit<br>1618    |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 23 January 2006.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 10,11,15-18,21-23,27,29-32,35-38 and 46-51 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 10,11 and 15 is/are allowed.

6)  Claim(s) 16-18,21-23,27,29-32,35-38 and 46-51 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

### **DETAILED ACTION**

Examiner acknowledges receipt of amendment and remarks filed 01/23/06. Claims 10, 11, 15-18, 21-23, 27, 29-32, 35-38, 46-48 and new claims 49-51 are pending.

1. The indicated allowability of claims 10, 11 and 15 is withdrawn in view of the art rejection below

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 10, 11, 15 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118) and Yajima et al. (US 5,972,373).

Daher discloses non-aqueous solution of tetracycline that comprises N-methyl-2-pyrrolidone, lauryl lactate, antioxidant, polysorbate solubilizer (abstract, column 1, lines 52 and 58; column 2, lines 6-12). The tetracycline composition of Daher does not contain polyvinylpyrrolidone. But, Yajima discloses a composition that contains tetracycline (column 2, lines 42 and 43), glycerol monolaurate or glycerol monostearate (column 2, lines 49-53), excipients (column 3, lines 19-29), disintegrants (column 3, lines 30-34), polyvinylpyrrolidone (column 3, line 38), antioxidant (column 3, lines 41-45), cellulose materials and dyes (column 3, lines 49-60) and polysorbate or polyoxyethylene-polyoxypropylene block copolymers (column 3,

lines 61-65). The compositions of Daher and Yajima individually contains tetracycline antibiotic. “It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). The viscosity recited is a property of the composition. And a composition/vehicle comprising polyvinylpyrrolidone, lauryl lactate and glycerol monolaurate or polysorbate would necessarily have the recited viscosity and there is no demonstration in applicants’ disclosure that the viscosity conveys special results/effects to the composition. Regarding claims 49-51, the person of ordinary skill in the art would know how to determine the amount one component relative to the other.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the composition of Daher and Yajima to form a third composition. One having ordinary skill in the art would have been motivated to combine the separate compositions of Daher and Yajima to form a third composition comprising tetracycline antibiotic, polyvinylpyrrolidone, polysorbate, lauryl lactate, glycerol monolaurate and excipients and antioxidants with the expectation that the third composition would be useful as an antibiotic composition (*In re Kerkhoven*). The comprising language of the claims is open and allows for the presence of other ingredients in the composition of the cited prior art.

4. The rejection of claims 16-18, 21-23, 27, 29-32, 35-38 and 46-48 under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118) and Yajima et al. (US 5,972,373) is withdrawn in view of the recitation of protein in the amended claims since the prior art

individually or combined do not teach the claimed composition of claim 16. Thus applicants' argument is persuasive in view of the amendment.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 16-18, 21-23, 27, 29-32, 35-38 and 46-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that the application was in possession of the claimed invention. There is no description in the specification for formulation that contains all and proteins.

There is no description exemplification for claim employing proteins other than human growth hormones and the specification does not inform the public of the limits of the monopoly asserted. The expression provided in the specification on page 13, first full paragraph represents

only an invitation to experiment regarding all the possible protein claimed in the instant application.

The recitation of amounts of the solvent, surfactant and polymer and ratios is new matter.

The as filed specification does not provide support for the recited amounts.

The rejection may be overcome by reciting the specific polymers disclosed and supported by the as filed specification and removal of the new matter from new claims 49-51.

8. Claims 49-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 49-51 recites the limitation "wherein the ratios" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 10, 11 and 15 do not recite ratios and therefore do not provide antecedent support for ratios.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
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Tech. Center 1600

